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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,312	06/12/2001	Laurie H. Glimcher	HUI-027CPDV	6498

959 7590 11/29/2004

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,312	GLIMCHER ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,32,34-54 and 57-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,32,34, 35, 37-54 and 57-60* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/086,010, filed May 27, 1998, now US patent 6,274,338, which a continuation in part of 09/030,579, filed February 24, 1998, now abandoned.

Applicants amendment filed August 13, 2004, has been received and entered. The specification has been amended. Claims 1-28, 30, 31, 33, 55-56 have been canceled. Claims have been amended. Claims 29, 32, 34-54, 57-60 are pending.

Election/Restrictions

Applicant's election without traverse of Group I was acknowledged. All pending claims 29, 32, 34-54 and 57-60 are currently under examination as they are drawn to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The disclosure objected to because on page 1, line 6, the grant information has been omitted and left blank is withdrawn.

Drawings

Upon review of the drawings and the specification it is found that the nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). Specifically, neither the drawing nor the brief description of the drawings has a SEQ ID NO associated with the sequences in the drawings.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claims

Claims 29, 31, 32, 34-54 and 57-60 objected to because the claims did not reflect the elected invention is withdrawn.

The amendment to the claims has obviated the basis of the objection.

Priority

Applicants have not addressed the basis of priority set forth in the previous office action. Accordingly, the priority date of this application, 09/086,010 is May 27, 1998.

As noted previously, this application is a Continuation-In-Part of application 09/030,579 with new matter introduced into Figures 1 and 2 (also SES ID NO 1 and 2), where in figure 1,

the applicant has insert nucleotides 515 to 720 previously represented as Ns in the parent application, and for figure 2, the applicant has inserted the corresponding new amino acids 172 to 240 previously reported as Ns.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 31, 32, 34-54 and 57-60 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims has addressed the specific basis of the each of the rejections.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 37 and 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 37 and 57 have been amended to recite and to encompass an invention that consists of specific constructs that have been deposited in ATCC. Since the constructs are

essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cell lines are not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make", may be satisfied by a deposit of cell lines. It is noted that Applicant has deposited the cell constructs, but there is no indication in the specification as to public availability. If the deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific cell lines have been deposited under the Budapest Treaty and that the cell lines will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

It the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of for the effective life of the patent, whichever is longer; and,

(d) a test of viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 32, 34, 35, 37-49, 51-54, 57-60 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hodge *et a*l. (Mol Cell Biol, 1995).

Claims 29, 34, 40, 42 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kataoka *et al.* (Mol Cell Biol, 1995).

Claims 29, 31, 34, 37, 40, 42, 43, 48 and 50 rejected under 35 U.S.C. 102(a) as being anticipated by Hedge *et a*l. (Mol Cell Biol, 1995) is withdrawn.

Applicants reiterate the basis of the rejection set forth in the previous office action (pages 13-14) and note the amendment to the claims to encompass SEQ ID NO: 2 or the NheI/XbaI fragment of pHu-c-Maf (page 14). Applicants argue that neither Hodge *et a*l., Kataoka *et a*l. nor Hedge *et a*l. now teach all the limitations of the claimed invention. See Applicants amendment, pages 13-14. Applicants arguments have been fully considered, and found persuasive in part.

With respect to the teachings of Hedges *et al.* homology searches demonstrate that the specific sequences of c-Maf disclosed appear to be different. Therefore, the rejection as being anticipated by Hedges *et al.* is withdrawn.

With respect to the remaining rejections, the amendment to the claims are noted, however Hodge *et al.* teaches the assay methodology and use of human cells. The present disclosure teaches that SEQ ID NO: 2 and the fragment cloned and deposited as pHu-c-Maf are human sequences. Since Hodge *et al.* teaches the use of human cells, and that these cells have genes that are responsive to c-Maf, these cells must contain the sequence disclosed as SEQ ID NO: 2 or that contained in the deposited as pHu-c-Maf clone. Similarly, Kataoka *et al.* use human cells in the assay methods taught.

As stated in the previous office action, Hodge *et a*l. teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on IL-4 expression (figure 5) and reporter genes such as CAT (figure 4). The cell types used in the assays include B cell M12B lymphoma and nonlymphoid HEPG2 cells. Because Hodge *et a*l. teach a cell based reporter assay method for assaying immune response as related to IL-4 and other reporter genes as it is related to the presence of c-Maf, the methods of Hodge *et a*l. anticipates the instant claims. Similarly, Kataoka *et a*l. teach a method wherein different compounds as represented by different transcriptional factors are provided in the context of c-maf in a cell based reporter assay in order to determine their affect on the reporter activity of luciferase (see figure 9). Because Kataoka *et a*l. teach a cell based reporter assay method for assaying a reporter gene as it is related to the presence of c-Maf, the methods of Kataoka *et a*l. anticipates the instant claims.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the

characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Because the assay and the materials used in the assay taught by Hodge *et al.* and Kataoka *et al.* are encompassed by those used in the instantly claimed method, the teachings of Hodge *et al.* and Kataoka *et al.* anticipate the claims.

Conclusion

No claim is allowed. Claims 36 and 50 are not rejected and free of the art of record, but is dependent on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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